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10/798,614

03/11/2004

Jose Luis Moctezuma de la Barrera

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EXAMINER

CHAO, ELMER M

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,614	<b>Applicant(s)</b> MOCTEZUMA DE LA BARRERA ET AL.	
	<b>Examiner</b> ELMER CHAO	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 39-42, 45, 46, 56-60, 63, 77-79, 84, 87 and 89-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-42, 45, 46, 56-60, 63, 77-79, 84, 87 and 89-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Acknowledgement is made of the amendment filed 8/26/2008.
2. Acknowledgement is made of the amendment and response to Election/Restriction filed 1/12/2009.

### ***Election/Restrictions***

3. Applicant's election with traverse of claims 39-42, 45, 46, 87, 89, and 90 in the reply filed on 1/12/2009 is acknowledged. The traversal is on the ground(s) that the present amendment filed 1/12/2009 overcomes the restriction requirement. Examiner has accordingly withdrawn the restriction requirement and has provided a rejection that addresses all of the pending claims in the current Office Action.

### ***Response to Arguments***

4. Regarding Applicants' arguments with respect to claims 56-60 and 79, Applicants argue that Bova doesn't teach attaching a substrate in a removable manner to an outer surface of a body (3rd paragraph, page 3, Arguments filed 8/26/2008). However, Examiner notes that Bova's teaching of placing the ultrasound device in contact with the body would satisfy the limitation of attaching in a removable manner. The claims of the instant application do not specify how the substrate should be attached, other than specifying that it should be "removably attached". Therefore, Bova's step of placing the device on the body would effectively make it so that the device is attached to the body (see fig. 1, the probe 22 is attached to the body). Furthermore, since Bova's device is

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"placed" on the patient, then it would also be removable after the operation is conducted. Additionally, Bova teaches that the probe is "held against the patient" (col. 8, lines 6-7), which would fully satisfy the action of "attaching" and would also inherently require "a means for attaching" (i.e. an operator's hand).

5. Regarding Applicant's arguments with respect to claims 39-42, 45, 46, 63, 76-78, 84, 87, and 89-95, Applicants argue that there is no motivation or suggestion to modify Bova with Acker (2nd paragraph, page 4, Arguments filed 8/26/2008). However, Examiner disagrees. As described in page 4 of the Office Action filed 6/25/2008, providing the magnetic tracker to Bova's system would enable a global positioning system for the anatomical structure. Such a modification is still usable with Bova because it would provide an improvement over the existing system by allowing a movable probe to detect the position of the anatomical structure regardless of where the probe is placed.

6. Applicants also argue that Acker does not teach a magnetic sensor with means for attachment to the anatomical structure (3rd paragraph, page 4, Arguments filed 8/26/2008). Examiner asserts that Acker's magnetic structure would be just as *capable of* attaching to an anatomical structure as it would be a probe (emphasis added). This is because the means provided that would allow an attachment to the probe would certainly also allow attachment to an anatomical structure. Furthermore, the recitation would be an example of functional language, and can be met with alternative interpretations of Acker's magnetic structure. For example, Acker's magnetic structure could be held onto the anatomy of a patient instead, thereby attaching it. Examiner

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advises Applicants to specify the means by which the magnetic structure would use to attach to an anatomical structure. Alternatively, Examiner informs Applicants that Acker explicitly teaches that the magnetic sensor is capable of being attached to an anatomical structure based on the fact that the sensor is attached to the probe, and the probe is inserted in the patient (third paragraph, last sentence, Arguments filed 8/26/2008). Therefore, the sensor is attachable to an anatomical structure by means of the probe.

7. Applicants also argue that the claims recite a magnetic transmitter rather than a magnetic sensor, which would be attached to the substrate (4th paragraph, page 4, Arguments filed 8/26/2008). Examiner had stated, "magnetic sensor in place of Bova et al.'s ultrasound transducer along with the magnetic sensor" (page 4 of the Office Action filed 6/25/2008). However, based on the recitation of "magnetic sensor" twice in the sentence, it was within the context for the reader to assume that "magnetic transmitter" should take the place of "magnetic sensor" in the aforementioned Office Action. Alternatively, the aforementioned Office Action's use of "magnetic sensor" refers to the magnetic sensor system, which operates only in conjunction with the magnetic transmitter, as one of ordinary skill in the art would understand. Furthermore, Examiner had stated earlier in the paragraph that Acker fails to teach the "magnetic transmitter" and "magnetic sensor". Therefore, the modification must involve teaching in Acker's transmitter and sensor. Otherwise, replacing Bova's probe with only a sensor without a transmitter would not function with the motivation provided by the Examiner, as one of ordinary skill in the art would understand.

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8. The Examiner has also included the double patenting rejection from the present application's earlier prosecution history for the purpose of keeping the record consistent. Examiner does note Applicants' earlier request to hold the provisional double patenting rejections in abeyance until allowable subject matter has been indicated in either the present application or application serial number 10/798,677 (page 13, Arguments filed 4/13/2007).

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. **Claims 39-42, 45, 46, 56-60, 63, and 78** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 18-25, 30, 49-50, 52-55, 71-76, 92-98, 108-113, and 132-136 of copending

Application No. 10/798,677. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application claims are merely broader than the copending application claims (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. **Claims 77** is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 22-25, 30, 53-55, 73-76, 94, and 111-113 of copending Application No. 10/798,677 in view of Danisch '257, further in view of Bartlett (U.S. 5,441,502). The copending Application and Danisch '257 do not teach a means comprising a pin. However, Bartlett '502 teaches anchoring means comprising of pins (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to use pins to anchor the fiber optic sensors or magnetic sensors to an anatomical structure in order to easily remove the pins after use, as often used in bone attachment applications (for motivation see col. 4, lines 31-48; col. 5, lines 3-9).

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **Claims 56-60, and 79** are rejected under 35 U.S.C. 102(b) as being anticipated by Bova et al. (U.S. 6,390,982). Bova et al. teaches a method of determining a change in position (col. 6, lines 45-64) using a surgical navigation system (Fig 2, Item 28); a substrate capable of being removably mounted to an outer surface of a body (Fig 2, Item 24), wherein the body includes a bony anatomical structure (Fig 2, see spinal cord illustration beneath Item 22); a sensor of three LEDs attached to the substrate that can be tracked by the surgical navigation system (Fig 2, Item 26); a positional device attached to the substrate that determines a position of the anatomical structure, wherein the positional device is an ultrasonic imaging device (Fig 2, Item 22) capable of 3D imaging and containing an array of multiple ultrasonic transducers (col. 2, lines 42-50; col. 6, lines 25-33); a first circuit for calculating a global position of the anatomical structure by correlating a position of the sensor and the position of the anatomical structure (Fig 2, Item 20; col. 6, L36-44); a second circuit for displaying the global position of the anatomical structure on a display unit (Fig 2, Item 20; col. 6, lines 65-57).

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



15. **Claims 39-42, 45, 63, 77, 84, 89, 92, and 93** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova et al. in view of Acker et al. (U.S. 5,558,091).

Regarding **claims 40-42, 45, 63, 77, 84, 89, 92, and 93**, Bova et al. teaches the limitations as discussed above, but fail to explicitly teach a magnetic transmitter attached to the substrate and a magnetic sensor with means for attachment to the anatomical structure. However, Acker et al. teach a magnetic transmitter and a magnetic sensor with means for attachment to the anatomical structure (claim 41 for example). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova et al. to instead use the magnetic transmitter in place of Bova et al.'s ultrasound transducer along with the magnetic sensor in order to provide global positioning of the anatomical structure relative to the room's fix frame of reference (col. 4, line 63 – col. 5, line 27, refer to superposition). Such a modification would also make it obvious to provide specific means necessary to attach the substrate to the body, close to the site of imaging in order to increase the efficiency of the interaction between the magnetic transmitter and sensors by minimizing the distance between them.

Regarding **claim 39**, such a modification would require the use of circuitry that would be able to determine a global position of the magnetic sensor.

16. **Claims 46, 78, 87, 90, 91, 94, and 95** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bova et al. in view Acker et al., further in view of Manglardi et al. (U.S. 5,665,092)

Regarding **claims 46, 78, 87, and 94**, Bova et al. and Acker et al. teach the limitations as discussed above but fail to explicitly teach a retrieval device being a wire. However, in the same field of endeavor, Manglardi et al. teach a retrieval device being a wire (Fig. 20). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova et al., Acker et al., and Manglardi et al. to teach a retrieval device being a wire in order to remove the sensors from the patient after imaging (for motivation see col. 7, lines 29-39).

Regarding **claims 90 and 95**, Bova et al., Acker et al., and Manglardi et al. teach the limitations as discussed above but fail to explicitly teach the wire being connected to the substrate. However, the wire is used for removal of the marker and would work as long as it is eventually used to remove the sensors. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova et al., Acker et al., and Manglardi et al. to teach attaching the substrate to the wire in order to conveniently remove the sensors as the substrate is removed from the area of interest (for motivation see col. 7, lines 29-39).

Regarding **claim 91**, Bova et al., Acker et al., and Manglardi et al. teach the limitations as discussed above but fail to explicitly teach placing the magnetic sensor through a sleeve with an impaction device. However, in the same field of endeavor, Manglardi et al. teach placing markers through a sleeve with an impaction device (Fig. 1). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Bova et al., Acker et al., and Manglardi et al. to teach

placing the magnetic sensor through a sleeve with an impaction device in order to achieve higher accuracy in placing the sensor in a desired location (col. 1, lines 26-35).

### ***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3/7/2009